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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/214,701	09/30/99	LOWELL G	406462000200

HM22/0828

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EXAMINER	
PARKIN, J	
ART UNIT	**PAPER NUMBER**
1648	10

DATE MAILED: 08/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/214,701	Lowell, G., et al.
Examiner	**Art Unit**
Jeffrey S. Parkin, Ph.D.	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 06/18/01 .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above, claim(s) 1-18 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 19-32 is/are rejected.

7) ☒ Claim(s) 19-32 is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☒ Other: Notice to Comply ...

Detailed Office Action

Status of the Claims

1. Applicants' election of Group II (claims 19-32) in paper no. 9 is acknowledged. Because applicant did not distinctly and specifically point out the purported errors in the restriction requirement, the election has been treated as an election without traverse (refer to M.P.E.P. § 818.03(a)). Claims 1-18 are withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention

37 C.F.R. § 1.821-1.825

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). Applicants are particularly directed toward pp. 31, 54, and 55 wherein various nucleotide and amino acid sequences are provided without accompanying sequence identifiers. However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Any questions regarding compliance with the sequence rules requirements specifically should be directed to the departments listed at the bottom of the Notice to Comply.

Information Disclosure Statement

3. The information disclosure statement filed 08 July, 1999, has been placed in the application file and the information referred to therein has been considered.

35 U.S.C. § 120

4. If applicant desires priority under 35 U.S.C. § 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of non-provisional application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application. If applicant desires priority based upon a National Stage filing, this information should also be referenced in the first sentence of the specification (i.e., This application is a National Stage entry of International Application No. PCT/CCPY/NNNNN, filed , 199N).

Disclosure

5. The disclosure is objected to because it fails to provide sequence identifiers (SEQ ID NOs.:) for the nucleotide and amino acid sequences set forth on pp. 31, 54, and 55. Appropriate correction is required.

Claim Objections

6. Claims 19-32 are objected to because they reference limitations set forth in a non-elected claim. Applicants should the claim language to include the desired limitations.

7. Claim 21 is objected to because it fails to provide sequence identifiers (SEQ ID NOs.:) for the amino acid sequences set forth. Appropriate correction is required.

35 U.S.C. § 112, Second Paragraph

8. Claims 19-32 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims reference features set forth in a non-elected claim which is confusing and ambiguous since the precise metes and bounds of the subject matter desired cannot be readily ascertained. Appropriate amendment of the claim language is required.

9. Claims 20-23 and 25-27 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims lack antecedent basis for "exogenous hydrophobic material" (claims 20 and 21), "protein" (claim 22), "antigen" (claim 25), and "protein or peptide" (claims 26 and 27). Appropriate correction is required.

35 U.S.C. § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (c) he has abandoned the invention.
>
> (d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to

> the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

11. Claims 19-21 and 26-32 are rejected under 35 U.S.C. § 102(e) as being anticipated by Lowell (1998). Lowell (1998) describes the preparation of vaccine compositions (e.g., see cols. 18-20) comprising an antigen (e.g., gp63) with an endogenous hydrophobic sequence (e.g., Ala-Ala-Gly) and an exogenously added hydrophobic sequence (e.g., lauroyl). Subjects were immunized with these compositions and neutralizing antibody responses generated that protected against challenge with the parent pathogen. Various methods of preparing these compositions were disclosed including dialysis and lyophilization (e.g., see cols. 6 and 7). The intranasal administration of these compositions to protect against mucosally-transmitted agents was also disclosed (e.g., see cols. 18-20). Accordingly, this teaching meets all of the claimed limitations.

35 U.S.C. § 103(a)

12. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as

> prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

14. Claims 22-26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lowell (1998) in view of VanCott *et al.* (1995). Lowell (1998) describes the preparation of vaccine compositions (e.g., see cols. 18-20) comprising an antigen (e.g., gp63) with an endogenous hydrophobic sequence (e.g., Ala-Ala-Gly) and an exogenously added hydrophobic sequence (e.g., lauroyl). Subjects were immunized with these compositions and neutralizing antibody responses generated that protected against challenge with the parent pathogen. Various methods of preparing these compositions were disclosed including dialysis and lyophilization (e.g., see cols. 6 and 7). The intranasal administration of these compositions to protect against mucosally-transmitted agents was also disclosed (e.g., see cols. 18-20). This teaching does not disclose the preparation of immunogens comprising oligomeric HIV-1 gp160. However, VanCott *et al.* (1995) describes the isolation and purification of oligomeric HIV-1 gp160 from isolates IIIb and 451. The authors reported (see Abstract, p. 103) that "The oligomeric nature of this gp160 protein preparation and high reactivity with

divergent mAbs and HIV-1 sera support the use of this protein as an HIV-1 immunogen." Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute the oligomeric HIV-1 gp160 provided by VanCott *et al.* (1995), with the leishmania gp63 protein described by Lowell (1998), since this would facilitate the generation of neutralizing antibodies against HIV-1.

Correspondence

15. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

16. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, James Housel or Laurie Scheiner, can be reached at (703) 308-4027 or (703) 308-1122, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

25 August, 2001

09/214,701

Application No.:_____

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: see P 2 of the office action

Applicant Must Provide:

☒ An initial ~~or substitute~~ computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial ~~or substitute~~ paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
For PatentIn software help, call (703) 308-6856

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE